Shaughnessy No.: 122804

Date Out of EFGWB: JAN 17 1989

JAN 17 1989

To: George T. LaRocca
Product Manager # 15
Registration Division (TS-767)

From: Paul Mastradone, Ph.D., Acting Chief
Environmental Chemistry Review Section 1
Environmental Fate and Ground Water Branch
Environmental Fate and Effects Division (TS-769-C)

THRU: Henry Jacoby, Acting Chief
Environmental Fate and Ground Water Branch/EFED (TS-769C)

FILE COPY

Attached, please find the EAB review of...

Reg./File # : 618-OI

Chemical Name: Avermectin

Type Product : Insecticide/miticide

Product Name : AGRI-MEK 0.15 EC

Company Name : MERCK

Purpose : EXPEDITE REVIEW of field dissipation study to support use on cotton, citrus, woody ornamentals, celery, and tomatoes.

Date Received: 12/8/88

Action Code: 181

Date Completed:

EFGWB#(s): 90227, 90225

Total Reviewing Time (decimal days): 3.5

Deferrals to:

_____ Ecological Effects Branch, EFED

_____ Science Integration & Policy Staff, EFED

_____ Non-Dietary Exposure Branch, HED

_____ Dietary Exposure Branch, HED

_____ Toxicology Branch, HED

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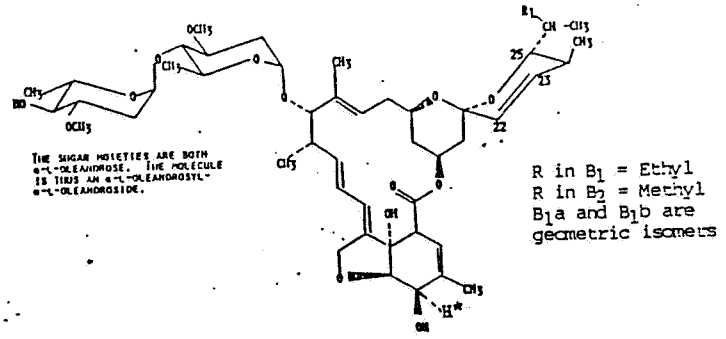
1. CHEMICAL: Common Name- abamectin (active ingredient)

Chemical Name- avermectin

Trade Name- AGRI-MEK 0.15 EC

Chemical Structure-

Avermectin (Mk-0936)



2. TEST MATERIAL: Abamectin 0.15 EC formulation.

3. STUDY/ACTION TYPE: The registrant requests an EXPEDITE REVIEW of a field dissipation study of abamectin/avermectin B_{1a} and its delta 8,9 isomer in support of registration on cotton, citrus, woody ornamentals, celery, and tomatoes. See attached memo of 12/14/88 from Anne Lindsay.

4. STUDY IDENTIFICATION:

- Norton, J.A. 1988. Soil leaching/soil dissipation study for abamectin 0.15 EC miticide/insecticide, Field trial summary for Merck Test No. 001-87-6045R, Merck and Co., Agricultural Research and Development, Three Bridges, NJ, Accession #409271-01.

- Tway, P.C. and P.G. Wertz. 1988. Soil residue chemistry data in support of applications for registratiion of abamectin, Merck No. 001-87-6045R, ADC No. 992, Accession #409271-02.

5. REVIEWED BY:

Herbert L. Manning, Ph.D.
Microbiologist, EFGWB/EFED

Signature: Herbert L. Manning
Date: JAN 17 1989

6. APPROVED BY:

Paul J. Mastradone, Ph.D.
Acting Chief, Section 1, EFGWB/EFED

Signature: Paul J Mastradone
Date: JAN 17

7. CONCLUSION:

The study is unacceptable at this time, since it is incomplete and is really an interim report. The data submitted were from "selected representative samples from one replicate." Data from the other three replicates will be reported at a later date.

Based upon the limited data provided, avermectin B_{1a} and delta 8,9 isomer did not leach below the 0-6 inch core depth after 10 applications at the maximum rate (0.02 lb ai/A) of 0.15 EC formulation. The reviewer-calculated half-life was 40 days. Residues declined from 8.15 ppb on day 0 to 1.65 ppb on day 90, posttreatment of 10 applications. Residues were not identified.

8. RECOMMENDATION:

The results of analyses of the three remaining soil core replicates should be submitted, as well as half-life calculations and decline curves for all the data.

9. BACKGROUND:

A. Introduction- The submission of this action to EFGWB is the result of a memo from Anne Lindsay (Registration Division) requesting an EXPEDITED REVIEW of a field leaching study to meet the first-time, food/feed uses of avermectin on cotton/citrus and the upcoming, spring growing season.

B. Direction for Use- A proposed label for the new uses on cotton and citrus was not included in the submission; however, the reviewed dissipation study indicates the maximum use is 0.02 lb ai/A using a 0.15 EC formulation.

10. DISCUSSION OF INDIVIDUAL STUDY:

See separate DATA EVALUATION RECORD.

11. COMPLETION OF ONE-LINER: Not applicable. Data was of an interim nature.

12. CBI APPENDIX: There is no CBI in this submission.

DATA EVALUATION RECORD

STUDY IDENIFICATION: Norton, J.A. 1988. Soil leaching/soil dissipation study for abamectin 0.15 EC miticide/insecticide.

REVIEWED BY:

Herbert L. Manning, Ph.D.
Microbiologist, EFGWB/EFED

Signature: Herbert L. Manning
Date: JAN 17 1989

APPROVED BY:

Paul J. Mastradone, Ph.D.
Acting Chief, Section 1, EFGWB/EFED

Signature: Paul J Mastradone
Date:

TYPE OF STUDY: Terrestrial Field Dissipation

CONCLUSIONS:

1. The study amounts to an interim report and is incomplete; the data submitted only covered selected samples from one of the four replicates. The study is unacceptable at this time, pending receipt of the data from the other three soil replicates.

2. Avermectin B_{1a}/delta 8,9 residue did not leach below 0-6 inch soil depth after 10 applications at the maximum rate of 0.02 lb ai/A of 0.15 EC (total of 200 ppb) to sandy loam soil. Sampled immediately after the 10^{th} application (0 day), avermectin residue was 8.15 ppb in 0-6 inch segment; at 28 days it was 4.25 ppb, at 60 days it was not quantifiable (<1 ppb), and at 90 days it was 1.65 ppb. Reviewer-calculated half-life, as determined by regression analysis, was 40. days (statistics and plot attached). No attempt was made to idenfify residues.

MATERIALS AND METHODS:

Ten weekly applications of 0.15 EC at the maximum rate of 0.02 lb ai/A (a total of 200 ppb) were made on celery growing in sandy loam soil (<1.25% OM). Plans to test celery for residues were abandoned because of poor development (4-5 inches). Soil cores were taken 0-12 inches before treatment and after each treatment, as well as after the 10^{th} treatment on days 1, 3, 7, 14, 28, 42, 60, 90, and 120. From day 28 to 120, additional cores were taken to cover 12-24 and 24-36 inch depths. The celery was a UTAH variety and the treated plot (0.17 acres) was located in Tulare County, CA. Watering of the plot was by Whirly-Bird orchard sprinklers and rainfall. The plot received a total of 24.96 acre inches of water. Collected core samples were frozen at $\leq$10°C and extracted within one month. Extraction of the soil was by acetonitrile:deionized water (1:1) and analysis for avermectin B_{1a} and its delta 8,9 isomer was by High Performance Liquid Chromatography (HPLC). Recovery of avermectin from fortified samples ranged from 81-100%.

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REPORTED RESULTS:

Table I summarizes the data from the "selected representative samples from one replicate." These data indicate the lack of movement of avermectin below 0-6 inches and its gradual dissipation from day 0 (8.15 ppb) through day 28 (4.25 ppb) to day 90 (1.65 ppb). Table II shows the recovery data. Soil characteristics of the core segments (0-12, 12-24, 24-36, and 36-48 inches) are also presented.

DISCUSSION:

1. The study amounts to being an interim report (and therefore an incomplete study), because the data submitted was only from selected samples of one of the four soil core replicates. Acceptance of the study will depend upon review of the remaining data.

2. Neither half-life determinations nor residue decline curves were provided. A regression analysis of the data was performed and yielded a half-life of 40 days (correlation coefficient squared = 0.98). The statistics and a semi-log plot of the data are attached.

3. If the soil core samples have been stored frozen for more than one month, than storage stability data should be included with the data on the other replicates.

DEC 4 1988

MEMORANDUM

SUBJECT: Request for Expedited Review of Petitions for 408 and 409 Tolerances and Section 3 Registration for Use of Avermectin B_1 and its Delta 8, 9-Isomer on Cotton, and Citrus (PP7F3500 and PP8F3592)

FROM: Anne E. Lindsay, Acting Director
Registration Division (TS-767C)

TO: William L. Burnam, Acting Director
Health Effects Division (TS-769C)

and
Anne L. Barton, Deputy Director
Environmental Fate and Effects Division (TS-769C)

On February 23, 1987 and December 7, 1987 Merck & Company, Inc. petitioned permanent tolerances and Section 3 registration for use of Avermectin B_1 and its delta 8, 9-isomer (AVM) on cotton and citrus respectively.

The major issues that need resolution are the characterization of the residues in animals; the characterization, identification and submission of toxicity data on the polar fraction of the residue in plants; additional field leaching studies and additional data on adverse effects to mammals and aquatic invertebrates. In an attempt to resolve these issues Merck & Company has submitted, in the last several months, data and/or rationale they believe addresses these issues and satisfies outstanding data requirements.

Since cotton and citrus are first time food/feed uses and the use season for these crops begins in early Spring, I am requesting your assistance in expediting DEB, TOX/IR, EFGWB and EEB reviews by January 24, 1989. I would

appreciate your cooperation in meeting this schedule. Attached are the pertinent submission record numbers for the information/data that is currently under review.

Attachment

RD A Heyward CG 12 8 88 X4421

EFGWB review dated 1/17/89 (100-895 + 100-898)

Page _____ is not included in this copy.

Pages 8 through 16 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

✓ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

REGRESSION ANALYSIS OF RESIDUE DECLINE DATA

NAME: H.L. MANNING DATE: 1/9/89

TITLE: FIELD DISSIPATION, AVERMECTIN, HALF-LIFE DETERMINATION, 0-6 inch depth

REMARKS: SEE TITLE B1a/delta 8,9

FILE NAME: AVERME RESIDUE LEVELS IN PPB INTERVALS IN DAYS

DATA ENTRIES 1 TO 3
8.15 at 0 DAYS 4.25 at 28 DAYS 1.65 at 90 DAYS

N= 3 SUM X= 118 SUM X†2= 8884 SUM Y= 4.04571 SUM Y†2= 6.74603 SUM X*Y= 85.5835
For the 95% confidence level, the appropriate 't' VALUE=6.3034 (For a one tailed test)

DF=1 CORRELATION COEFFICIENT=.99412 CORRELATION COEFFICIENT SQUARED=.988274
Y-INTERCEPT= 2.03043 RELATIVE % ERROR OF THE SLOPE= 10.9% % LOSS PER DAY= 1.72%

SLOPE= -.017, its UPPER 95% CL= -.005 and its LOWER 95% CL= -.029
HALF LIFE= 40 DAYS, its UPPER 95% CL= 127.6 DAYS and its LOWER 95% CL= 23.7 DAYS

DAY ZERO LEVEL=7.617 PPB, its UPPER 95% CL=20.92 PPB and its LOWER 95% CL=2.774 PPB

FIELD DISSIPATION, AVERMECTIN, HALF-LIFE DETERMINATION, 0-6 inch depth

SEE TITLE

(...=UPPER 95% CON. LIMIT)